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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,524	02/11/2004	Gosse Jan Adema	DX0670KB1B	8025

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EXAMINER	
BUNNER, BRIDGET E	
ART UNIT	**PAPER NUMBER**
1647	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/27/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/777,524	ADEMA ET AL.	
	Examiner	Art Unit	
	Bridget E. Bunner	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21 and 23-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21 and 23-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08 September 2006 has been entered.

Status of Application, Amendments and/or Claims

The amendment of 08 September 2006 has been entered in full. Claims 1-20, 22, and 30-32 are cancelled.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 21 and 23-29 are under consideration in the instant application.

Withdrawn Objections and/or Rejections

1. The objections to the specification as set forth at pg 3 of the previous Office Action (05 April 2006) are *withdrawn* in view of the amended abstract and specification (08 September 2006). At pg 6 of the Response of 08 September 2006, Applicant indicated that they are unaware of any rule that requires that amendments be made in the specification as filed rather than the published application. The Examiner pointed out at pg 3 in the previous Office Action of 05 April 2006 that Applicant's amendments to the published patent application were not entered because they were not in accordance with 37 CFR 1.121 (see also MPEP § 714). MPEP § 714.01 specifically states that "[a]ny amendment filed after the filing date of the application is

not part of the original disclosure of the application. See MPEP § 706.03(o) regarding new matter. When the Office publishes the application under 35 U.S.C. 122(b), the Office may include preliminary amendments in the patent application publication. See MPEP § 1121". MPEP §714.01 continues to state that "[t]he only format for an amendment to the specification (other than the claims) that is usable for publication is a substitute specification in compliance with 37 CFR 1.121(b)(3) and 1.125". Applicant's attempt to the amend the specification of the publication in the previous Response of 10 January 2006 was after the filing date of the application (thus, not a preliminary amendment) and was after publication.

Claim Rejections - 35 USC § 101 and 35 U.S.C. § 112, first paragraph

2. Claims 21 and 23-29 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility. Novel biological molecules lack well established utility and must undergo extensive experimentation. The basis for this rejection is set forth for claims 21 and 23-29 at pg 4-9 of the previous Office Action (05 April 2006) and for claims 21-29 at pg 3-6 of the Office Action of 12 July 2005.

The claims are directed to a substantially pure or isolated polypeptide comprising the amino acid sequence of SEQ ID NO: 2. The claims recite a composition comprising the polypeptide and a polypeptide fused to a detection or purification tag. The claims recite a kit comprising the polypeptide. The claims recite that the polypeptide is recombinantly produced.

Applicant's arguments (08 September 2006), as they pertain to the rejections have been fully considered but are not deemed to be persuasive for the following reasons.

(i) At pg 7 of the Response of 08 September 2006, Applicant asserts that a disclosed utility for the claimed subject matter satisfies the utility requirement under § 101 absent evidence which would cast doubt on the objective truth of the disclosed utility. Applicant states that there is no legal requirement that the disclosed utility must be supported by conclusive experimental data and cites MPEP § 2107.02 (III)(A). Applicant argues that the Office is requiring that a certain and exact disclosure of the biological role of the FDF03 protein and its significance must be described if the specification is to fulfill the utility requirement of §§ 101 and 112. Applicant contends that the Office is requiring proof beyond a reasonable doubt regarding the functional role of the FDF03 protein in monocytes and cells of the myelomonocytic lineage.

Applicant's arguments have been fully considered but are not found to be persuasive. The truth, or credibility, of the assertion of utility has not been questioned. Rather, the rejection sets forth that the assertion of utility is not specific or substantial. The Examiner acknowledges that "[in] most cases, an Applicant's assertion of utility creates a presumption of utility that will be sufficient to satisfy the utility requirement of 35 U.S.C. 101 (MPEP § 2107.02 (section III)). However, in the previous Office Actions of 05 April 2006 and 12 July 2005, the Examiner made a *prima facie* showing that the claimed invention lacks utility and provided sufficient evidentiary basis for factual assumptions relied upon in establishing the *prima facie* showing. Essentially, Applicant has not provided evidence to demonstrate that the claimed FDF03 polypeptide of the instant application is supported by a specific and substantial asserted utility or a well established utility. The Examiner has fully considered all evidence of record and has responded to each substantive element of Applicant's response (see points (ii) -(vi) below). It is noted to Applicant that MPEP § 2107.02 (part VI) also states that "only where the totality of the record continues to

show that the asserted utility is not specific, substantial, and credible should a rejection based on lack of utility be maintained".

(ii) At the bottom of pg 7 and at pg 8 of the Response, Applicant asserts that FDF03 has a specific, substantial, and credible utility as a regulator of antigen presentation. Applicant points out that the specification discloses that FDF03 is an Ig receptor superfamily member. Applicant cites de Vet et al. (J Biol Chem 276: 42070, 2001) and states that it is well accepted that the Ig receptor superfamily constitutes a large number of cell proteins involved in the immune system and cellular recognition. Applicant submits that in view of the restricted expression and known functions of the Ig receptor superfamily, the specification identifies a specific utility for FDF03 as a regulator of hematopoietic cells including those involved in antigen presentation (monocytes and dendritic cells; specification pg 68-69). At the bottom of pg 8 of the Response, Applicant explains that monocytes upon activation differentiate into macrophages which can act as antigen presenting cells. Applicant states that dendritic cells are professional or specialized antigen presenting cells that must be activated prior to presenting antigen to other cells. Applicant cites Exhibit A and points to 14 different references that were provided previously which recognize and/or demonstrate that the FDF03 negatively regulates, i.e., inhibits, activation of dendritic cells and monocytes.

Applicant's arguments have been considered but are not found to be persuasive. The specification of the instant application teaches that FDF03 is a type I transmembrane protein with Ig-like extracellular portion, indicating that this protein is a receptor member of the Ig superfamily (pg 3, lines 5-7; pg 17, lines 1-8; pg 42, lines 27-31). As Applicant points out, de

Vet discloses that "[t]he Ig superfamily receptors constitutes a large group of cell surface proteins involved in the immune system and cellular recognition" (pg 42070, col 1). The state of the art at the time the invention was made also teaches that "[t]he immunoglobulin superfamily (IgSF) includes a large number of cell surface proteins with diverse biological functions" and that IgSF molecules have diverse functional roles in immunity and cell recognition (Huang et al., Biopolymers 43: 367-382, 1997; pg 367, col 1; Table I; pg 368, col 1, lines 11-14), Thus, the state of the art clearly evidences that each immunoglobulin superfamily molecule has a different function and each new member should be evaluated empirically to determine the precise function it has.

The specification also does not teach any methods or working examples to demonstrate that the FDF03 polypeptide of the instant application has any functional activity. At the time the instant application was filed, one skilled in the art would not have known the utility and function of polypeptide in the instant specification, even if it was a putative Ig receptor expressed on monocytes and dendritic cells because, as discussed in the related art above, immunoglobulin superfamily members include a wide range of receptors with diverse biological activities. Additionally, evidence of mere expression on a tissue or cell type is not tantamount to a showing of a functional role of the FDF03 polypeptide. Basic research to determine the functional properties of the claimed protein is still required. Although the specification discloses that "[t]he proteins likely play a role in regulation or development of hematopoietic cells, e.g. lymphoid cells, which affect immunological responses, e.g. antigen presentation and the resulting effector functions" (pg 68, line 37 through pg 69, lines 1-3), this asserted utility is not specific or substantial because it is not clear what specific role or function FDF03 is correlated with (such as

proliferation, differentiation, apoptosis, cell-cell adhesion, regulation of cytokine production, T cell activation, antigen capture and presentation, among others) or which specific hematopoietic cells FDF03 regulates or develops.

As discussed in the previous Office Action of 05 April 2006, the specification at the time of filing does not disclose that FDF03 is involved in antigen presentation or negatively regulates activation of dendritic cells and monocytes. The specification at the time of filing also does not disclose that FDF03 is an inhibitory receptor or any physiological activity of FDF03. Although the post-filing date references, which study FDF03, are interesting, they clearly indicate that at the time of filing, further characterization of FDF03 was required and Applicant's invention was incomplete. As stated in *In re Fisher,* "[A]n application must show that an invention is useful to the public as disclosed in its current form, not that it may prove useful at some future date after further research. Simply put, to satisfy the 'substantial' utility requirement, an asserted use must show that the claimed invention has a significant and presently available benefit to the public." (see *Fisher*, 421 F.3d at 1371, 76 USPQ2d at 1230; see also MPEP § 2107.01(B)).

In the instant case, the claimed FDF03 polypeptide is not disclosed as having an activity that can be specifically useful. Thus, further research is required to identify or reasonably confirm a specific and substantial utility. See MPEP § 2107.01(I)(C), for example. Such further research requirements make it make it clear that the asserted utility is not yet in currently available form, i.e., it is not substantial. This further experimentation is part of the act of invention and until it has been undertaken, Appellant's claimed invention is incomplete. See *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct., 1966), wherein the court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention

> with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", "Congress intended that no patent be granted on a chemical compound whose sole "utility" consists of its potential role as an object of use-testing", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion."

In conclusion, the functional properties of the claimed FDF03 polypeptide were not well characterized at the time of filing of the instant application and one skilled in the art the art would not find the utility of the claimed polypeptide to be obvious.

(iii) At the top of pg 9 of the Response, Applicant contends that the dendritic cell data provided is sufficient because only a minimal utility is required. Applicant argues that there is no legal requirement for definitive evidence and disclosure of the exact mechanism and function of FDF03 in the regulation of cells of the myeloid lineage or in antigen presentation. Applicant cites *Juicy Whip, Inc. v. Orange Bang, Inc.*, 51 USPQ2d 1700, 1702 (Fed. Cir. 1999) and emphasizes that because the threshold of utility is minimal under 35 U.S.C. § 101, an invention is useful if it is merely capable of providing some identifiable benefit.

Applicant's arguments have been fully considered but are not found to be persuasive. A specification can meet the legal requirements of utility and enablement for a new polypeptide as long as the specification discloses at least one specific and substantial asserted utility for the new polypeptide, or a well-established utility for the claimed polypeptide that would be *prima facie* obvious to the skilled artisan. A hypothetical example may serve to clarify. For example, a hypothetical specification discloses that a claimed polynucleotide encodes an ion channel, which is asserted to be specifically involved in nociception. The hypothetical specification provides the

evidence by showing that alteration of the channel activity leads to the change in perception of pain. The claimed polynucleotide in the hypothetical example would not be rejected under 35 U.S.C. § 101 and § 112, first paragraph, as it has utility and is enabled as a target for pain alleviating drugs. However, such is not the fact pattern here. The instant disclosure of a novel immunoglobulin superfamily member fails to provide any factual evidence that this specific FDF03 polypeptide is associated with any particular disease, condition, or physiological process.

As discussed in point (ii) above, the specification at the time of filing does not disclose that FDF03 negatively regulates activation of dendritic cells and monocytes. The specification at the time of filing also does not disclose that FDF03 is an inhibitory receptor or any physiological activity of FDF03. Although the post-filing date references, which study FDF03, are interesting, they clearly indicate that at the time of filing, further characterization of FDF03 was required and Applicant's invention was incomplete. As stated in *In re Fisher,* "[A]n application must show that an invention is useful to the public as disclosed in its current form, not that it may prove useful at some future date after further research. Simply put, to satisfy the 'substantial' utility requirement, an asserted use must show that the claimed invention has a significant and presently available benefit to the public." (see *Fisher*, 421 F.3d at 1371, 76 USPQ2d at 1230; see also MPEP § 2107.01(B)).

(iv) At the bottom of pg 9, Applicant asserts that objective evidence demonstrates that antibodies against the FDF03 protein inhibit degranulation of mast cells. Applicant contends that the Examiner has offered no evidence which cast doubt on the objective truth of the evidence

presented in Dr. Phillips declaration. Applicant argues that the Examiner has not argued that the ability to regulate hematopoietic cells itself lacks utility. Applicant submits that it is the recognition that FDF03 regulates hematopoietic cells together with the supporting objective evidence that gives the protein its utility, not whether or not its full potential or any exact mechanism of action was elucidated and disclosed. At the top of pg 10 and the bottom of pg 11 of the Response, Applicant reiterates that FDF03 role in hematopoietic regulation, e.g. regulating mast cell activity, is specific, substantial, in its real world use of modulating immune responses involving mast cell degranulation, and credible based on the objective evidence in Dr. Phillips' declaration.

Applicant's arguments have been fully considered but are not found to be persuasive. As discussed in the previous Office Action, the declaration of Dr. Joseph Phillips filed under 37 CFR 1.132 (10 January 2006) is insufficient to overcome the rejection of claims 21 and 23-29 based upon lack of utility and/or inoperativeness under 35 U.S.C. 101. Specifically, the declaration of Dr. Phillips states that "results of these experiments showed that agonist antibodies raised against FDF03 could prevent mast cell degranulation, thus impairing the inflammatory cascade associated with mast cell function" (pg 3, for example). However, this asserted utility for antibodies against FDF03 (to inhibit the degranulation of mast cells, thus preventing mast cell mediated inflammation) is not supported by the instant specification as filed. For utility to be "well established", it must be specific and substantial. The specification of the instant application only broadly teaches that "[t]he proteins likely play a role in regulation or development of hematopoietic cells, e.g. lymphoid cells, which affect immunological responses, e.g. antigen presentation and the resulting effector functions" (pg 68, line 37 through pg 69, lines

1-3). However, this asserted utility is not specific or substantial because at the time of filing, it was not clear what specific role or function FDF03 is correlated with (such as proliferation, differentiation, apoptosis, cell-cell adhesion, regulation of cytokine production, T cell activation, antigen capture and presentation) or which specific hematopoietic cells FDF03 regulates or develops. Again, the specification of the instant application does not specifically disclose regulating mast cell activity or FDF03 involvement in mast cell degranulation. As stated in *In re Fisher,* "[A]n application must show that an invention is useful to the public as disclosed in its current form, not that it may prove useful at some future date after further research. Simply put, to satisfy the 'substantial' utility requirement, an asserted use must show that the claimed invention has a significant and presently available benefit to the public." (see *Fisher*, 421 F.3d at 1371, 76 USPQ2d at 1230; see also MPEP § 2107.01(B)).

(v) At the bottom of pg 6 and at pg 10 of the Response, Applicant argues that FDF03 has a specific, substantial, and credible utility as a diagnostic marker on cells of myelomonocytic lineage for reasons already made of record. Applicant contends that the Examiner has not challenged the validity of this utility. Applicant asserts that the utility of FDF03 as an identifier of a specific cell population is sufficiently specific, substantial, and credible to meet the utility requirement without disclosing a biological role or significance. Applicant argues that dendritic cells are recognized as the most potent of antigen presenting cells in the art and therefore, the ability to use FDF03 as a marker for dendritic cells provides an identifiable benefit to the researcher or physician. Applicant submits that greater sophistication in cell identification using

such markers assists the researcher in, for example, cell separation applications and the physician in increasing diagnostic strength in dendritic cell-based diseases.

Applicant's arguments have been fully considered but are not found to be persuasive. The truth, or credibility, of the assertion of utility as a diagnostic marker on cells of myelomonocytic lineage has not been questioned. Rather, the rejection sets forth that the assertion of utility is not specific or substantial. As discussed at pg 7-8 of the previous Office Action, the asserted patentable utility of using FDF03 as a marker to identify dendritic cells or cells myelomonocytic lineage is not specific or substantial because the instant application does not disclose the biological role of the FDF03 protein or its significance. Evidence of mere expression on a tissue or cell type is not tantamount to a showing of a functional role of the FDF03 polypeptide. Basic research to determine the functional properties of the claimed protein is still required. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

Furthermore, the asserted patentable utility of using FDF03 as a marker to identify dendritic cells or cells myelomonocytic lineage is not specific or substantial because one skilled in the art would not readily use the polypeptide as a cell marker in a real world sense since the protein has not been shown to be specific to limited cell types and is not associated with any disease or disorder. The specification of the instant application only teaches that FDF03 is expressed on the cell surface of monocytes and dendritic cells. The declaration of Dr. Phillips submitted under 37 C.F.R. § 132 on 10 January 2006 indicates that FDF03 is not expressed on T cells, B cells, or NK cells. However, the specification and post-filing date references do not provide any evidence to indicate that FDF03 *is not* expressed on other cells of the immune

system, such as stem cells, progenitor cells, stromal cells, eosinophils, basophils, megakaryocytes, just to name a few. There is also no indication in the specification that neutrophils, which are derived from a monocyte progenitor cell, express FDF03. In other words, the specification does not teach definitive differential cell expression of FDF03. Thus, if one skilled in the art was to perform a cell separation technique on a blood sample using FDF03 as a marker, he/she may not simply isolate myelomonocytic cells or dendritic cells, as asserted by Applicant. Thus, the asserted utility as a marker for myelomonocytic cells and dendritic cells is not specific or substantial.

(vi) At the bottom of pg 10 of the Response, Applicant asserts that the law does not require the certain and exact data on biological role or function demanded by the Examiner. Applicant argues that "the Board" recently acknowledged the absence of such a requirement in *Ex parte* Hedrick (Exhibit C). At pg 11 of the Response, Applicant reviews the *Ex parte* Hedrick and contends that the facts of the instant application are very similar to those of the Board decision discussed in *Ex parte* Hedrick.

Applicant's arguments have been fully considered but are not found to be persuasive. The current rejection is in compliance with the most currently-published version of the Utility Guidelines which require that all biological inventions must have credible, specific and substantial ("real world") utility. Additionally, each patent application is examined on its own merits. The invention that was deemed allowable in one patent has no bearing on this application. It is also noted that the opinion in support of the decision of the Board of Patent Appeals and Interferences in the case that Applicant has identified as *Ex parte* Hedrick

(Application No. 09/770,528) was not written for publication and is not binding precedent of the Board.

3. Claims 21 and 23-29 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. The basis for this rejection is set forth for claims 21 and 23-29 at pg 9 of the previous Office Action (05 April 2006) and for claims 21-29 at pg 6 of the Office Action of 12 July 2005.

Applicant's arguments (08 September 2006), as they pertain to the rejections have been fully considered but are not deemed to be persuasive for the following reasons.

Specifically, since Applicant has not provided evidence to demonstrate that the FDF03 polypeptide of SEQ ID NO: 2 has a specific and substantial asserted utility or a well established utility, one skilled in the art would not know how to use the claimed invention. It is noted that the instant specification is required to teach one skilled in the art how to make and use the FDF03 polypeptide.

Conclusion

No claims are allowable.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Elgert, K. Immunology, understanding the immune system. New York: Wiley-Liss, Inc., 1996; pg 25

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (571) 272-0881. The examiner can normally be reached on 8:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BEB
Art Unit 1647
18 December 2006

Bridget E. Bunner

BRIDGET BUNNER
PATENT EXAMINER